

<b>Case Number:</b>	CM15-0187581		
<b>Date Assigned:</b>	09/29/2015	<b>Date of Injury:</b>	10/26/2010
<b>Decision Date:</b>	12/01/2015	<b>UR Denial Date:</b>	08/24/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/23/2015

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:  
 State(s) of Licensure: California  
 Certification(s)/Specialty: Emergency Medicine

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 61 year old male who sustained an industrial injury on 10/26/2010. Medical records indicated the worker has diagnoses that include chronic pain, Lumbar disc displacement, Lumbar Radiculopathy, right wrist strain, right plantaris tear. In the provider notes of 08-10-2015 the worker presents for pain medicine follow-up visit and re-examination. He reported neck pain, and low back pain that is frequent. The low back pain radiates down both legs and is accompanied by numbness and tingling. He rates his pain as an average of 6 on a scale of 0-10 on average with medications since last visit, and an average 8 on the scale of 0-10 without medications. The notes of 80-10-2015 have contradictory statements, one saying his pain is reported as improved since his last visits, and the second stating, "None of the medications help relieve the pain. The pain is reported as recently worsened." The evaluation continues with the worker reporting ongoing activity of daily living limitations in the following areas due to pain: sleep, sex, and the activities of daily living over the past month. A Transforaminal Epidural Steroid Injection bilateral L5-S1 (08-07-2015) was reported to have given a good (50-80%) overall improvement. The worker reported good functional improvement in the following areas: decrease in pain medication requirements and improved mobility. The worker is getting routine urine drug screens and has been counseled in restrictions of alcohol intake and specific activities while on opiates. The worker has had no emergency room visits for pain relief in the past month. He reports ten or more flares in the past month but pain did not restrict his activities of daily living. Pain has kept the worker from sexual relations, sitting, sleeping, and standing. Inconsistency of absent controlled medication in the worker's urine

screening were discussed with the worker and it was noted that he had not taken as much medication at the time. The plan is to decrease medication as indicated. Medications include, Zolpidem, Hydrocodone and Gabapentin (since at least 10-27-2014), Lidocaine 5% patch and Enovarx-Ibuprofen were newly prescribed on 08-10-2015. According to notes of 08-10-2015, and the worker is currently working full-time without restrictions other than that of being restricted from one extremely physical job exertion. 1. Enovarx-Ibuprofen 10% kit #1. 2. Lidocaine 5% patch #30 with 1 refill. 3. Urine drug testing. 4. Zolpidem 10/325mg #60. 5. Hydrocodone 10/325mg #60. 6. Gabapentin 300mg #60. A utilization review decision 08/24/2015: Certified: Hydrocodone 10/325mg #60; Gabapentin 300mg #60. And Non-Certified: Enovarx- Ibuprofen 10% kit #; 1 Lidocaine 5% patch #30 with 1 refill; Urine drug testing.

### **IMR ISSUES, DECISIONS AND RATIONALES**

The Final Determination was based on decisions for the disputed items/services set forth below:

**Enovarx-Ibuprofen 10% kit #1: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjoldal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. In this case, as indicated above, the patient would not qualify for the use of this medication based on the treatment duration. As such, the request is not medically necessary.

**Lidocaine 5% patch #30 with 1 refill: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The request is for the use of a Lidoderm patch to aid in pain relief. The MTUS guidelines state that its use is indicated for post herpetic neuralgia after an initial trial of an anti-epileptic medication. Further research is needed to recommend use for chronic neuropathic disorders besides post-herpetic neuralgia. In this case, the patient does not have a diagnosis documented which would justify the use of Lidoderm patches. As such, the request is not medically necessary.

**Urine drug testing:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Urine drug testing.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic)/Urine drug testing (UDT).

**Decision rationale:** The request is for a urine drug screen. The ODG states the following regarding this topic: Recommended as a tool to monitor compliance with prescribed substances, identify use of undisclosed substances, and uncover diversion of prescribed substances. The test should be used in conjunction with other clinical information when decisions are to be made to continue, adjust or discontinue treatment. This information includes clinical observation, results of addiction screening, pill counts, and prescription drug monitoring reports. The prescribing clinician should also pay close attention to information provided by family members, other providers and pharmacy personnel. The frequency of urine drug testing may be dictated by state and local laws. Indications for UDT: At the onset of treatment: (1) UDT is recommended at the onset of treatment of a new patient who is already receiving a controlled substance or when chronic opioid management is considered. Urine drug testing is not generally recommended in acute treatment settings (i.e. when opioids are required for nociceptive pain). (2) In cases in which the patient asks for a specific drug. This is particularly the case if this drug has high abuse potential, the patient refuses other drug treatment and/or changes in scheduled drugs, or refuses generic drug substitution. (3) If the patient has a positive or "at risk" addiction screen on evaluation. This may also include evidence of a history of comorbid psychiatric disorder such as depression, anxiety, bipolar disorder, and/or personality disorder. See Opioids, screening tests for risk of addiction & misuse. (4) If aberrant behavior or misuse is suspected and/or detected. See Opioids, indicators for addiction & misuse. Ongoing monitoring: (1) If a patient has evidence of a "high risk" of addiction (including evidence of a comorbid psychiatric disorder (such as depression, anxiety, attention-deficit disorder, obsessive-compulsive disorder, bipolar disorder, and/or schizophrenia), has a history of aberrant behavior, personal or family history of substance dependence (addiction), or a personal history of sexual or physical trauma, ongoing urine drug testing is indicated as an adjunct to monitoring along with clinical exams and pill counts. See Opioids, tools for risk stratification & monitoring. (2) If dose increases are not decreasing pain and increasing function, consideration of UDT should be made to aid in evaluating medication compliance and adherence. The frequency of drug testing is indicated below: Patients at "low risk" of addiction/aberrant behavior should be tested within six months of initiation of therapy and on a yearly basis thereafter. There is no reason to perform

confirmatory testing unless the test is inappropriate or there are unexpected results. If required, confirmatory testing should be for the questioned drugs only. Patients at "moderate risk" for addiction/aberrant behavior are recommended for point-of-contact screening 2 to 3 times a year with confirmatory testing for inappropriate or unexplained results. This includes patients undergoing prescribed opioid changes without success, patients with a stable addiction disorder, those patients in unstable and/or dysfunction social situations, and for those patients with comorbid psychiatric pathology. Patients at "high risk" of adverse outcomes may require testing as often as once per month. This category generally includes individuals with active substance abuse disorders. In this case, a urine drug screen is not supported by the guidelines. This is secondary to inadequate documentation of risk level commensurate to the frequency of evaluation requested. As such, it is not medically necessary.

### **Zolpidem 10/325mg #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Stress & Mental Illness Chapter, Zolpidem, Non-Benzodiazepine sedative-hypnotics.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental(stress)/ Zolpidem (Ambien).

**Decision rationale:** The request is for the use of zolpidem. The official disability guidelines state the following regarding the use of this medication: Not recommended for long-term use, but recommended for short-term use. See Insomnia treatment for zolpidem (brand names Ambien, Edluar, Intermezzo, Zolpimist). See also the Pain Chapter. Zolpidem is approved for the short-term (usually two to six weeks) treatment of insomnia. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. Ambien CR offers no significant clinical advantage over regular release zolpidem, and Ambien CR causes a greater frequency of dizziness, drowsiness, and headache compared to immediate release zolpidem. Due to adverse effects, FDA now requires lower doses for zolpidem. The ER product is still more risky than IR. Even at the lower dose of Ambien CR now recommended by the FDA, 15% of women and 5% of men still had high levels of the drug in their system in the morning. (Pain Chapter) Emergency department (ED) visits for adverse reactions related to zolpidem increased by almost 220% in a recent 5-year period, according to the Substance Abuse and Mental Health Services Administration (SAMHSA). Women and the elderly appear to be most prone to adverse reactions linked to zolpidem. Doctors should look at alternative strategies for treating insomnia such as sleep hygiene. By 2010 there were 64,175 ED visits involving zolpidem. The report stresses that zolpidem should be used safely for only a short period of time. (SAMHSA, 2013) Zolpidem (Ambien) increases the ability to remember images, but only those that have negative or highly arousing content. The findings have potential ramifications for patients prescribed zolpidem for relief of insomnia due to anxiety disorders, including posttraumatic stress disorder (PTSD). Physicians should watch out for this counter therapeutic effect in patients with anxiety

disorders and PTSD, because these are people who already have heightened memory for negative and high-arousal memories. The study also identified sleep spindles as the mechanism that enables the brain to consolidate emotional memory. Sleep spindles are brief bursts of brain activity that occur primarily during non-rapid eye movement (REM) sleep. (Kaestner, 2013) New analysis from SAMHSA shows that overmedicating with zolpidem led to a near doubling of emergency department (ED) visits during the periods 2005-2006 and 2009-2010. (SAMHSA, 2014). In this case, zolpidem is not indicated. This is secondary to the prolonged duration of use. As such, the request is not medically necessary.